

COMMISSION IMPLEMENTING REGULATION (EU) 2020/106
of 23 January 2020
concerning the authorisation of sodium formate as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of sodium formate. That application was accompanied by the particulars and documents required under Article 7 (3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of sodium formate as a feed additive for all animal species to be classified in the category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 30 April 2015 ⁽²⁾ and 26 February 2019 ⁽³⁾ that, under the proposed conditions of use, the sodium formate does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the substance is mildly irritating to eyes and a skin sensitiser. In addition, given that the exposure to sodium formate via inhalation is considered to present a risk to unprotected workers handling the additive, it is prudent to consider it as a respiratory irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to users of the additive. The Authority also concluded that sodium formate liquid has the potential to be efficacious as hygiene condition enhancer in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of sodium formate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of sodium formate should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'hygiene condition enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2015; 13(5):4113.

⁽³⁾ EFSA Journal 2019; 17(3):5645.

*Article 2***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 January 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of formic acid/kg of complete feedingstuff with a moisture content of 12 %			
Technological additives: hygiene condition enhancers								
1k237	Sodium formate	<i>Additive composition</i> Liquid form ≥ 15 % sodium formate ≤ 75 % formic acid ≤ 25 % water	All animal species except pigs	—	—	10 000 (formic acid equivalent)	<ol style="list-style-type: none"> In the directions for use of the additive and premixture, the storage conditions shall be indicated. The mixture of different sources of formic acid shall not exceed the permitted maximum content in complete feedingstuffs. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. 	13 February 2030
		<i>Characterisation of the active substance</i> Sodium formate ≥ 15 % (liquid form) Formic acid ≤ 75 % Produced by chemical synthesis	Pigs	—	—	12 000 (formic acid equivalent)		
		<i>Analytical method ⁽¹⁾</i> Determination of sodium in feed additives: EN ISO 6869: atomic absorption spectrometry (AAS) or EN 15 510: inductively coupled plasma atomic emission spectrometry, (ICP-AES). Determination of total formate in feed additives: EN 15909 reverse phase HPLC with UV detection (RP-HPLC-UV). Determination of total formate in premixtures and feedingstuffs: Ion-exclusion high performance liquid chromatography with UV or with refractive index detection (HPLC-UV/RI) or Ion chromatography method equipped with electrical conductivity detection (IC-ECD).						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>